K/22010

510(K) SUMMARY

JUL 2 0 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c). The assigned 510(k) number is:

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 8188 5604 Fax: +86 755 2658 2680

Contact Person:

Zhai Pei Shenzhen Mindray Bio-medical Electronics Co., LTD

Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: June 15, 2012

2. <u>Device Name</u>: Z6 Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

- 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
- 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
- 21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

Z6 Diagnostic Ultrasound System is a general purpose, portable, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Power/Dirpower Mode, or the combined mode (i.e. B/M-Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

4. Intended Use:

The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intraoperative(abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vessel and urology exams.

5. Comparison with Predicate Devices:

Z6 Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1	Mindray	M5	K102991,K083001
2	Mindray	M7	K100830
3	Mindray	DC-7	K103583
4	Mindray	DP-6900	K090912

They have the similar technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

Z6 Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical safety standards. This device has been designed to meet the following standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, IEC 62304, IEC 62366,UL 60601-1, ISO14971, UD 2, UD 3 and ISO 10993-1.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the Z6 Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

JUL 2 0 2012

Shenzhen Mindray Bio-Medical Electronics Co., Ltd. % Mr. Jeff D. Rongero Senior Project Manager UL LLC 12 Laboratory Drive RESEARCH TRIANGLE PARK NC 27709

Re: K122010

Trade/Device Name: Z6 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: June 29, 2012 Received: July 9, 2012

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Z6 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

3C5P	·	CB10-4P
	•	
<u>6C2P</u>		<u>V10-4BP</u>
<u>6CV1P</u>		<u>7LT4P</u>
<u>7L4P</u>		<u>6LE7P</u>
<u>7L5P</u>		<u>2P2P</u>
I.14-6P		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Jeffrey Ballyns at (301) 796-6105.

Sincerely Yours,

Janine M. Morris

Acting Director

Division of Radiological Devices

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Indications for Use

	510(k) Number (if known):
	Device Name: Z6 Diagnostic Ultrasound System .
•	Indications For Use:
	The Z6 Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It's intended for use in fetal, abdominal, intraoperative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, transvaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), peripheral vessel and urology exams.
	Prescription Use X AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)
	(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
	Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Office of Ir	(Division Sign-Off) Division of Radiological Devices 1 Vitro Diagnostic Device Evaluation and Safety Page 1 of1_

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Diagnostic Ultrasound Indications for Use Form

S	ys	te	n

· Transducer

Model:

Z6 Diagnostic Ultrasound System

510(k) Number(s)

	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic									
Fetal	N,	N	N	L	N	N	N	Note1,2	
Abdominal	N	N	N	N	N	N	N	Note 1,2	
Intraoperative (specify)*	N	N	N		N	N	N	Note 1,2	
Intraoperative (Neuro)									
Laparoscopic									
Pediatric	N	N	N	N	N	N	N	Note 1, 2	
Small organ(specify)**	N	N	N		N	N	N	Note 1,2	
Neonatal Cephalic	N	N	N	N	N	N	N.	Note 1, 2	
Adult Cephalic	N	N	N		N	N	N .	Note1, 2	
Trans-rectal	N	N	N	Ī	N	N	N	Note 1, 2	
Trans-vaginal	N	N	N		N	N	N	Note 1, 2	
Trans-urethral	,								
Trans-esoph.(non-Card.)				<u> </u>					
Musculo-skeletal Conventional	7	N	N		N	N	N	Note 1,2	
Musculo-skeletal Superficial	N	N	N	<u> </u>	N	N	N	Note 1,2	
Intravascular				1					
Cardiac Adult	N	N	N	N	N	N·	N	Note 1,2	
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2	
Intravascular (Cardiac)									
Trans-esoph.(Cardiac)									
Intra-Cardiac									
Peripheral Vessel	N	N	N		N	N	N_	Note1, 2	
Other (specify)***	N	N	N		N	N	N N	Note 1, 2	

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional comments: Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW

*Intraoperative includes abdominal, thoracic, and vascular

**Small organ-breast, thyroid, testes

***Other use includes Urology.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

Note 2: Biopsy Guidance

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Prescription USE (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

	Diagn	ostic l	Ultrasou	nd Indi	cations for	Use Form		
System	-			Transdu	исег	×		
Model:			3C5P					
510(k) Number(s)				-				
					Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N.		N .	N	N	Note 1, 2
Abdominal	N	N	N		N	N	N	Note 1, 2
Intraoperative (specify)*								
Intraoperative (Neuro) .								
Laparoscopic				<u> </u>				
Pediatric	N	N	N	<u> </u>	N	N	N	Note 1, 2
Small organ(specify)**								
Neonatal Cephalic				L			<u> </u>	
Adult Cephalic								
Trans-rectal						·	_	
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)						_		
Musculo-skeletal	N	N	N	Į.	N	N	l _N	Note 1, 2
Conventional	IN .	14	14		IN	1	1,	11010 1, 2
Musculo-skeletal Superficial					<u> </u>			
Intravascular	<u> </u>							<u></u>
Cardiac Adult			•					
Cardiac Pediatric								
Intravascular (Cardiac)		Ĺ		<u> </u>				
Trans-esoph.(Cardiac)								•
Intra-Cardiac						·		
Peripheral Vessel	N	Ν	N		N_	N	N	Note 1, 2
Other (specify)***		<u> </u>	<u> </u>				ļ	
N=new indication; P=previou								
Additional comments:Combi	ned mo	des: F	3+M, PW	/+B, Co!	lor+B, Pow	ver+B, Color	r+B+PW, Po	wer+B+PW
*Intraoperative in	cludes	abdon	ninal, tho	гасіс, ar	nd vascular	•		
**Small organ-bro	ast, th	yroid,	testes					
***Other use incl								
Note 1: Tissue Ha	rmonic	Imag	ing. The	feature	does not us	e contrast a	gents.	
Note 2: Biopsy G	uidance	9						
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Concurrence of CDRH, Off	ice of	Device	e Evalua	tion(OI	DE)			

	Diagn	ostic l	Ultrasou	nd Indi	cations for	r Use Form	,		
System		_		Transd	исег	×			
Model:			6C2P						
510(k) Number(s)									
	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic				Ī					
Fetal									
Abdominal	N	N	N		N	N	N	Note 1, 2	
Intraoperative (specify)*									
Intraoperative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	Note 1, 2	
Small organ(specify)**									
Neonatal Cephalic	N	N	N		N	N	N	Note 1, 2	
Adult Cephalic	N.	N	N		N	N	N_	Note 1, 2	
Trans-rectal									
Trans-vaginal	[
Trans-urethral		<u></u>		ļ					
Trans-esoph.(non-Card.)	<u> </u>								
Musculo-skeletal									
Conventional		<u> </u>							
Musculo-skeletal Superficial			<u> </u>	<u> </u>					
Intravascular		<u>l</u>	<u> </u>						
Cardiac Adult									
Cardiac Pediatric]			<u> </u>					
Intravascular (Cardiac)					<u> </u>				
Trans-esoph.(Cardiac)									
Intra-Cardiac									
Peripheral Vessel									
Other (specify)***								·	
N=new indication; P=previou	ısly cle	ared b	y FDA; l	E=added	under Ap	pendix E			
Additional comments:Combi	ned mo	odes: E	3+M, PW	/+B, Col	lor+B, Pov	ver+B, Color	+B+PW, Po	wer+B+PW	
*Intraoperative in				racic, ar	id vascular				
**Small organ-bro	east, th	yroid,	testes						
***Other use incl	udes U	rology	/.						
Note 1: Tissue Ha			ing. The	feature (does not us	se contrast ag	gents.		
Note 2: Biopsy G	uidance	е						<u> </u>	
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Office of In Vitro Diagnostic Device Evaluation and Safety

	Diagn	ostic l	Ultrasou	nd Indi	cations for	r Use Form				
System				Transdu	ıcer	×				
Model:		6	CV1P ·							
510(k) Number(s)					•					
` ,					•					
	Mode of Operation									
Clinical Application				T	Color	Amplitude	Combined			
l ''	В	M	PWD	CWD	Doppler	Doppler	(specify)	Other (specify)		
Ophthalmic				i						
Fetal	N	N	N		N	N	N	Note 1, 2		
Abdominal										
Intraoperative (specify)*										
Intraoperative (Neuro)				· ·						
Laparoscopic										
Pediatric .										
Small organ(specify)**					<u> </u>	<u> </u>				
Neonatal Cephalic										
Adult Cephalic										
Trans-rectal	N	N	N	1	N	N	· N	Note 1, 2		
Trans-vaginal	N	N	N		N	N	N	Note 1, 2		
Trans-urethral										
Trans-esoph.(non-Card.)										
Musculo-skeletal				Ī						
Conventional .										
Musculo-skeletal Superficial	\Box]							
Intravascular	Γ	-		-	[
Cardiac Adult						,				
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph.(Cardiac)										
Intra-Cardiac				[
Peripheral Vessel	Ī							•		
Other (specify)***	N	N	N		N _	N	N	Note 1, 2		
N=new indication; P=previou	ısly cle	ared b	y FDA;	E=added	under Ap	pendix E				
Additional comments:Combi	ned mo	des: E	s+M, PW	/+B, Col	or+B, Pow	ver+B, Color	+B+PW, Po	wer+B+PW		
*Intraoperative in										
**Small organ-bro	east, th	yroid,	testes				•			
***Other use incl	udes U	rology								
Note 1: Tissue Ha	.rmonic	Imag	ing. The	feature o	does not us	se contrast ag	gents.			
Note 2: Biopsy G										
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System	Diagn	ostic	Ultrasou	ind Indi Transd		r Use Form ×	,	
Model:			7L4P	211111111111111111111111111111111111111	2001	-	•	
510(k) Number(s)			, 2, 1,		•			
Jio(k) (valitoei(s)					-			
	i	•	•		Mode of	f Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	•							
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)		<u> </u>					,	
Laparoscopic								
Pediatric	·N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	·N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic			i					
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal	7	.,	N		N	N	, , ,	Note 1.2
Conventional	N	N	N	i	N	N	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular			I					
Cardiac Adult			T					
Cardiac Pediatric				Ţ				
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac				T				
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***		T						
N=new indication; P=previou	sly cle	ared b	y FDA;	E=added	l under Ap	pendix E		
Additional comments:Combin							+B+PW, Po	wer+B+PW
*Intraoperative inc								
**Small organ-bre	ast, th	yroid,	testes					
***Other use inclu	ıdes U	rology	<i>'</i> .				•	
Note 1: Tissue Ha				feature	does not us	e contrast ag	gents.	
Note 2: Biopsy Gu	idance	2						
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	Diagn	ostic l	Ultrasou	nd Indi	cations for	r Use Form		
System	_			Transd		× '		
Model:		•	7L5P				•	
510(k) Number(s)					•			
• • • • • • • • • • • • • • • • • • • •					•			
	T				. Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								,
Fetal		· -						
Abdominal	N	N	N		N	N	N	Note 1,2
Intraoperative (specify)*	Ì							
Intraoperative (Neuro)								
Laparoscopic	\Box			 				
Pediatric	N	N	N	<u> </u>	N	N	N	Note 1,2
Small organ(specify)**	N	N ·	N		N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal				1				
Trans-vaginal				-				
Trans-urethral								
Trans-esoph.(non-Card.)	T			-				
Musculo-skeletal	N	N	N		N	N	N	Note 1,2
Conventional	IN .	l ^{IN} .	IN		N	IN	N	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular								
Cardiac Adult	Ι							
Cardiac Pediatric			·					
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)] -				
Intra-Cardiac			1					
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***								
N=new indication; P=previou	ısly cle	ared b	y FDA; I	=added	under App	pendix E		
Additional comments:Combi	ned mo	des: E	3+M, PW	+B, Col	or+B, Pow	er+B, Color	+B+PW, Po	wer+B+PW
*Intraoperative in	cludes	abdon	inal, tho	racic, an	d vascular			
**Small organ-bre	ast, th	yroid,	testes	•				
***Other use incl	udes U	rology	·				,	
Note 1: Tissue Ha			ing. The	feature o	loes not us	e contrast ag	gents.	
Note 2: Biopsy G								
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	Diagn	ostic	Ultrasou	nd Indi	cations for	r Use Form		
System	Ü			Transd		×		
Model:		L	.14-6P				•	,
510(k) Number(s)					•		•	
			,		•			
	Γ				Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	. N	N	Note 1,2
Intraoperative (specify)*								
Intraoperative (Neuro)						•		
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2
Small organ(specify)**	N	N	N	J	N	N	N	Note 1,2
Neonatal Cephalic	N	N	N		N	N	N	Note 1,2
Adult Cephalic								
Trans-rectal								
Trans-vaginal	1							
Trans-urethral		l						
Trans-esoph.(non-Card.)							,	
Musculo-skeletal	N	N	N		N	N	N	Note 1,2
Conventional	IN	IN .	IN		IN	IN	IN	Note 1,2
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2
Intravascular		<u>l</u>				<u> </u>		
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)		<u> </u>						
Trans-esoph.(Cardiac)				·				
Intra-Cardiac		<u> </u>			<u> </u>			
Peripheral Vessel	N	N	N		N	N	N	Note 1,2
Other (specify)***] ,			<u> </u>				
N=new indication; P=previou	ısly cle	ared b	y FDA;	E=added	under Ap	pendix E		
Additional comments:Combi	ned mo	des: E	3+M, PW	/+B, Col	or+B, Pow	ver+B, Coloi	+B+PW, Po	wer+B+PW
*Intraoperative in	cludes	abdon	ninal, tho	гасіс, аг	ıd vascular	•		
**Small organ-br	east, th	yroid,	testes					
***Other use incl								
Note 1: Tissue Ha			ing. The	feature (does not us	se contrast a	gents.	
Note 2: Biopsy G	uidanc	е						
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•	Diagn	ostic i	Ultrasou	nd Indi	cations for	r Use Form		
System				Transd	ucer ,	×		
Model:		CI	310-4P					
510(k) Number(s)								
					Mode of	Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal								·
Intraoperative (specify)*				ŀ				
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	· N		N	N	N	Note 1,2
Trans-vaginal				·				
Trans-urethral								
Trans-esoph.(non-Card.)							·	
Musculo-skeletal								
Conventional								
Musculo-skeletal Superficial							•	
Intravascular				1	<u> </u>			
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vessel								
Other (specify)***	N	N	N		N	N	N	Note 1,2
N=new indication; P=previou	sly cle	ared b	y FDA; l	E=added	under App	pendix E		
Additional comments:Combi	ned mo	des: B	+M, PW	'+B, Col	or+B, Pow	er+B, Color	+B+PW, Po	wer+B+PW
*Intraoperative in	cludes	abdom	inal, tho	racic, an	d vascular			
**Small organ-bre	ast, th	yroid,	testes					
***Other use incl								
Note 1: Tissue Ha	rmonic	Imag	ing. The	feature o	loes not us	e contrast ag	gents.	
Note 2: Biopsy Gu							,	
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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form Transducer System V10-4BP Model: 510(k) Number(s) Mode of Operation Color Amplitude Combined Clinical Application **PWD CWD** Other (specify) В M Doppler Doppler (specify) Ophthalmic N N N N N N Note 1, 2 Fetal Abdominal Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic Pediatric Small organ(specify)** Neonatal Cephalic Adult Cephalic Note 1, 2 Frans-rectal N Ν N N N Ν N Note 1, 2 Trans-vaginal N N Ν N l'rans-urethral Frans-esoph.(non-Card.) Musculo-skeletal Conventional Musculo-skeletal Superficial Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Peripheral Vessel Note 1, 2 Other (specify)*** Ν N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW *Intraoperative includes abdominal, thoracic, and vascular **Small organ-breast, thyroid, testes ***Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

Office of In Vitro Diagnostic Device Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form Transducer System 7LT4P Model: 510(k) Number(s) Mode of Operation Clinical Application Color Amplitude Combined **PWD CWD** В Other (specify) Doppler Doppler (specify) Ophthalmic Fetal N N Ν N N N Note 1,2 Abdominal N N N N N Ν Note 1,2 Intraoperative (specify)* Intraoperative (Neuro) Laparoscopic N N N Note 1,2 N N N Pediatric Note 1,2 Small organ(specify)** Ν Ν N Ν N Ν Neonatal Cephalic N Ν N Ν N N Note 1,2 ă. Adult Cephalic Frans-rectal Frans-vaginal Frans-urethral Frans-esoph.(non-Card.) Musculo-skeletal Ν Ν N N Ν N Note 1,2 Conventional Ν N N N Note 1,2 Musculo-skeletal Superficial N Ν Intravascular Cardiac Adult Cardiac Pediatric Intravascular (Cardiac) Trans-esoph.(Cardiac) Intra-Cardiac Note 1,2 Peripheral Vessel N N Ν Other (specify)*** N=new indication; P=previously cleared by FDA; E=added under Appendix E Additional comments: Combined modes: B+M, PW+B, Color+B, Power+B, Color+B+PW, Power+B+PW *Intraoperative includes abdominal, thoracic, and vascular **Small organ-breast, thyroid, testes ***Other use includes Urology. Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents. Note 2: Biopsy Guidance (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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	Diagnostic Ultrasound Indications for Use Form									
System				Transd	ucer	×		•		
Model:		6	LE7P		_		`•			
510(k) Number(s)										
	Mode of Operation									
Clinical Application		T.,	D.175	CUZD	Color	Amplitude	Combined	04 (
	B	М	PWD	CWD	Doppler	Doppler	(specify)	Other (specify)		
Ophthalmic										
Fetal										
Abdominal	\Box			1						
Intraoperative (specify)*	 									
Intraoperative (Neuro)										
Laparoscopic	1						········			
Pediatric	\vdash			1	1					
Small organ(specify)**					-					
Neonatal Cephalic	1									
Adult Cephalic	1						·····			
Trans-rectal	N	N	N		N	N	N	Note 1,2		
Trans-vaginal	1									
Trans-urethral	1									
Trans-esoph.(non-Card.)	1	•	1							
Musculo-skeletal	T		1	 						
Conventional			1							
Musculo-skeletal Superficial					<u> </u>					
Intravascular	1			1	1			-		
Cardiac Adult	+-	-	—	1						
Cardiac Pediatric			<u> </u>	-						
Intravascular (Cardiac)				<u> </u>	<u> </u>					
Trans-esoph.(Cardiac)			1	İ						
Intra-Cardiac	1		1							
Peripheral Vessel			1				·			
Other (specify)***	N	N	N		N	N	N	Note 1,2		
N=new indication; P=previous	ısly cle		v FDA: I	E=added	l under Ap	pendix E		<u> </u>		
Additional comments:Combi							/ +Color+ B.	Power + PW +B		
*Intraoperative in								,		
**Small organ-br						, i,				
***Other use incl										
Note 1: Tissue Ha				feature	does not us	se contrast as	gents.	-		
Note 2: Biopsy G			· · · · ·					· · · · · · · · · · · · · · · · · · ·		
(PLEASE DO NOT WRITE			IS LINE	-CONTI	NUE ON A	ANOTHER	PAGE IF NE	EEDED)		
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System •	Transducer					x			
Model:	2P2P								
510(k) Number(s)					_				
					-				
	Mode of Operation								
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic				1					
Fetal			1	<u> </u>					
Abdominal	N	N	N	N	N	N	N	Note 1,2	
Intraoperative (specify)*		1.		1					
Intraoperative (Neuro)				T :		<u> </u>			
Laparoscopic				1		1			
Pediatric	N	N	N	N	N	N	N	Note 1,2	
Small organ(specify)**		·						,	
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2	
Adult Cephalic									
Trans-rectal		<u> </u>		 		<u> </u>			
Trans-vaginal						 			
Trans-urethral			†			<u> </u>	-		
Trans-esoph.(non-Card.)				1		 		· ·	
Musculo-skeletal		-	 	 					
Conventional	i			}					
Musculo-skeletal Superficial			 	†		<u> </u>			
Intravascular		<u> </u>		 				·	
Cardiac Adult	N	N	N	N	N	N	. N	Note 1,2	
Cardiac Pediatric	N	N	N	N	N	N N	N N	Note 1,2	
Intravascular (Cardiac)	- ``	 	 	 :`	• • • • • • • • • • • • • • • • • • •	 	· · · · · · · · · · · · · · · · · · ·	1,010 1,2	
Trans-esoph.(Cardiac)		 	†						
Intra-Cardiac			 	 	<u> </u>	· · · · · · · · · · · · · · · · · · ·			
Peripheral Vessel	 	 	<u> </u>	 	<u> </u>				
Other (specify)***		 	 						
N=new indication; P=previou	slv cle	ared b	v FDA· l	F=added	under An	nendiy E		 	
Additional comments:Combin							+R+PW Po	wer+R+PW	
*Intraoperative inc									
**Small organ-bre				,					
***Other use inclu									
Note 1: Tissue Har				feature of	loes not us	e contrast ac	ents.		
Note8: Biopsy Gui							, 		
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